

**Massachusetts Department of Mental Health
Elizabeth Childs, M.D., Commissioner**

**Psychoactive Medication for Children and Adolescents:
Orientation for Parents, Guardians, and Others**

The Children and Adolescents'
Psychoactive Medication Workgroup

Division of Child and Adolescent Services
Office of Clinical and Professional Services

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PREFACE

This booklet presents principles for the use of psychoactive medication in children and adolescents. It offers information about medication treatment. It does not recommend specific medications or doses. The Booklet was developed by a group convened by the Division of Child and Adolescent Services of the Massachusetts Department of Mental Health. The group included representatives of the Department of Social Services, the Division of Medical Assistance, the Juvenile Court Clinic, the Massachusetts Behavioral Health Partnership, the New England Council of Child Psychiatry, the Parent Professional Advocacy League, and representative hospitals and health care organizations. Participants are listed in Appendix VII, Members of Working Group.

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TABLE OF CONTENTS

I.	INTRODUCTION.....	7
	Childhood Disorder: Epidemiology	7
	Psychoactive Medication for Children and	
	Adolescents: A Rapidly Evolving Field	7
	New Knowledge, New Ways to Help Children	
	and Adolescents	8
	This Orientation Booklet.....	9
II.	MEDICATION TREATMENT IN CHILDREN AND	
	ADOLESCENTS: WHAT CAN IT HELP WITH?	9
III.	MEDICATIONS IN CURRENT USE	10
	A. Psychostimulants	11
	B. Antidepressants	11
	C. Mood Stabilizers	13
	D. Antipsychotics	14
	E. Other Medications	16
IV.	PRINCIPLES OF PRACTICE	17
	A. Assessment	17
	B. Planning and Contracting for Treatment.....	20
	1. Articulating Problems, Target Symptoms,	
	and Goals	20
	2. Selecting Agents.....	21
	3. Planning Treatment and Monitoring:	
	Monitoring, Anticipating Problems,	
	Seeking Consultation	22
	4. Informed Consent: Who, What, How,	
	When, Where, To Whom	23
	C. Integration of Treatment.....	26
	D. Communication and Record Keeping.....	27
	E. Continuity of Care	27
V.	AREAS OF CONTROVERSY	28
	A. Attention Deficit-Hyperactivity Disorder.....	28
	B. Bipolar Disorder	30
	C. Use of Antipsychotics (aka Neuroleptics)	31
	D. Post-Traumatic States	32
	E. Children and Adolescents with	
	Developmental Disabilities.....	33
	F. Extreme Behavioral Dyscontrol	
	(Aggressive and Self-Injurious).....	34
	G. Involuntary Treatment	35

H.	Adverse Side Effects	36
VI.	CLIENT-PARENT EDUCATION.....	36
VII.	MEMBERS OF WORKING GROUP.....	39

I. INTRODUCTION

Childhood Disorder: Epidemiology and Diagnosis

Eleven percent of children and adolescents in the U.S. ages 9 to 17 are estimated to have a diagnosable mental or addictive disorder with significant functional impairment (Surgeon General's Report on Mental Health, 1999). Consistent with this estimate, 4 million youths may suffer from a major mental illness and have significant impairments at home, at school, and with peers. Those with developmental impairment are at greater risk of symptoms and disorders. Abuse or neglect, a major risk factor for later mental disorder, is estimated to be suffered by 3 million children and adolescents per year in the United States.

Psychoactive Medication for Children and Adolescents: A Rapidly Evolving Field

Children and adolescents with serious emotional disturbance are receiving psychoactive medication more often than in the past.

Several factors have contributed to this increase. Some reflect scientific progress and changes in attitudes towards children and adolescents' mental health, such as:

- advances in the neurosciences, recognizing that brain functioning is altered in mental disorders of childhood and adolescence;
- epidemiological evidence relating childhood symptoms to adult disorders;
- increasing recognition of children and adolescents' mental health needs and readiness to define those needs in terms of brain functioning; and
- the introduction of psychoactive agents with fewer immediate side effects and less likelihood of long-term, serious side effects, especially tardive dyskinesia.

In addition, the pattern of children and adolescents' mental health services has changed:

- "Acuity" has shifted. Children and adolescents with serious emotional disturbance are no longer treated only in hospitals, but often in foster homes and community residences, facilities that have not historically treated children and adolescents with serious behavioral symptoms. More children and adolescents are being hospitalized, but for shorter lengths of stay, resulting in a need for interventions likely to have a rapid effect, such as pharmacotherapy.

Much medication practice in children and adolescents is based on clinical experience, not on controlled clinical trials. This practice occurs with other pediatric medications as well, not just

with those psychoactive medications, because most pharmacological research has been done with adults. The Food and Drug Administration relies on controlled clinical trials in order to approve a specific indication for a medicine. Few of the medicines used in children and adolescents have been evaluated in that way. Uses of medications for indications or populations (such as use with children and adolescents) for which no systematic data are available are called “off label”.

For those with responsibility for children and adolescents, now called Personal Representatives,* these changes raise important questions:

- How do Personal Representatives and other interested parties assess medication recommendations made by a physician?
- With limited data about possible benefit and risk, particularly in growing children and adolescents, how do clinicians make recommendations? How do Personal Representatives authorize treatment?
- How can clinicians best inform Personal Representatives of their choices and how can Personal Representatives best get information?

This booklet responds to these questions. We hope to contribute to public education, in keeping with one of the goals in the Surgeon General’s Action Plan for Children’s Mental Health, namely to “make available information on effective prevention and treatment interventions...”

New Knowledge, New Ways to Help Children and Adolescents

Progress in pediatric psychopharmacology gives us new opportunities to help children and adolescents. Child psychiatrists and other clinicians are learning more and more, both from organized clinical trials and from observations of individual children and adolescents. Some observations are unexpected: for instance, a child whose lifelong sensory defensiveness improves dramatically on risperidone (Risperdal) prescribed for other symptoms; or a child whose capacity for empathy appears to increase on naltrexone (Revia), prescribed for severe self-mutilating behavior.

Such fortuitous observations may point to new ways to understand children and adolescents and to help the individual child or adolescent. They may also help lead to new clinical research or neuroscientific investigations.

This Booklet

- informs interested parties about medication;
- acknowledges the rapid evolution of the field of pharmacotherapy for children and adolescents;
- offers principles of good care; and
- acknowledges areas where controversy exists.

This document does not recommend particular medications or doses.

*HIPAA (the Health Insurance Portability and Accountability Act), effective May 2003, defines the person who is legally authorized to make health care decisions as a "Personal Representative."

The Personal Representative may be the minor's parent, a court appointed guardian (with scope to cover health care decisions) or an entity (e.g. DSS or DYS).

II. MEDICATION TREATMENT IN CHILDREN AND ADOLESCENTS: WHAT CAN IT HELP WITH?

Medication may help with many problems, but not with everything. Medication may help with disturbances of mood (low mood or depression, elevated mood [hypomania or mania] and unstable mood), disturbances of attention (attention deficit-hyperactivity disorder), anxiety symptoms including compulsions and flashbacks and other sequelae of trauma, some impulse control problems, and confused thinking and perceptions.

Medication will not “bring up to age” a child or adolescent with delayed development. Medication might, however, help with specified symptoms. Medications will not take away the disturbed language and ways of relating seen in children and adolescents with autism or other pervasive developmental disorders. But medication might help with associated problems like obsessive-compulsive behavior or scattered attention. Medication will not help a child or adolescent who has a problem telling the truth. But if lying is a symptom of a major depression, antidepressant medication might help with the depression. Medication will not help with “normal” childhood sadness but may help with clinical depression.

Are we treating “symptoms” (specific problem behaviors) or “disorders” (diagnoses)? This question can be puzzling; the difference between symptoms and disorders can be confusing. Parents bring their children and adolescents for help with *symptoms*, such as poor school performance, irritability, tics, and depressed mood. But the same symptoms may come from many different *disorders*, which may reflect differences in brain chemistry and which require different medication. Because choice of medicine should be guided by a diagnosis, doctors usually diagnose a disorder before recommending a trial of medication.

For instance, a child or adolescent’s poor attention may be associated with attention deficit-hyperactivity disorder (ADHD), major depression, psychosis, metabolic disorder, or traumatic brain injury. The indicated medicine will be different with each disorder. Irritability may characterize children and adolescents with brain injury or metabolic disorder, as well as ADHD, depression, Tourette’s Syndrome, or an adjustment disorder.

But while a specific diagnosis *may* point to disorder-specific treatment, it is not always possible to base clinical practice on diagnosis alone. Psychiatric diagnoses are “conventions,” that is, agreements among physicians about ways to classify people’s troubles. These conventions, though shared by doctors and endorsed by insurance companies, differ from the ways that families, and whole cultures, talk about their children’s behavior. Professionals’ discussion of children’s troubles must respect a family’s or culture’s ways of telling the story in addition to using the “scientific” tools of DSM diagnoses.

In addition, DSM diagnoses “fit the patient” less well in child psychiatry than with adults; to adequately describe their adaptive troubles, many children and adolescents are given multiple DSM diagnoses. Future research may refine our present diagnoses, add new ones, or encourage use of different approaches to assessment of children and adolescents (e.g., dimensional diagnosis). In the meantime, clinicians are trying to help children and adolescents with specific symptoms, the targets of prescribed medications.

Parents, guardians and professionals must keep in mind both symptoms, diagnoses, and the languages that parents, children and adolescents use to talk about their troubles.

III. MEDICATIONS IN CURRENT USE

This section lists medications in current use and their indications. A more extensive discussion of the efficacy and safety of medications commonly prescribed to children and adolescents has been published in a special section of the Journal of the American Academy of Child and Adolescent Psychiatry (Vitiello and Jensen, eds., 1999). That review is organized according to class of agents; separate articles review stimulants, antidepressants, mood stabilizers, antipsychotics, anxiolytics, adrenergics and naltrexone.

A. Psychostimulants

<u>Generic Name</u>	<u>Brand Name</u>
Methylphenidate.....	Ritalin
	Methylin
Sustained-release methylphenidate	Concerta
	Ritalin SR
	Metadate
Dextroamphetamine	Dexedrine
	Dextrostat
Pemoline.....	Cylert
Dextroamphetamine and Amphetamine.....	Adderal

Psychostimulants have been used for decades to treat children who are hyperactive and inattentive. These medications reduce hyperactivity and inattention and improve behavioral control and cognitive performance. (These effects are similar to those of caffeine, another stimulant.) Research indicates that stimulants are effective long-term. Children and adolescents vary considerably in their response to stimulants; many children and adolescents experience only partial symptom relief.

B. Antidepressants

Selective Serotonin Reuptake Inhibitors (SSRI's)

<u>Generic Name</u>	<u>Brand Name</u>
Fluoxetine.....	Prozac
Sertraline	Zoloft
Paroxetine.....	Paxil

Fluvoxamine	Luvox
Citalopram	Celexa
Escitalopram.....	Lexapro

Tricyclic Antidepressants (TCAs)

Nortriptyline	Pamelor
Desipramine.....	Norpramin
Imipramine	Tofranil
Clomipramine	Anafranil
Amitriptyline	Elavil

Monoamine Oxidase Inhibitors (MAOI's)

Tranylcypromine	Parnate
Phenelzine	Nardil

Other Antidepressants

Venlafaxine	Effexor
Nefazodone.....	Serzone
Trazodone	Desyrel
Bupropion.....	Wellbutrin
Mirtazapine.....	Remeron

Selective serotonin reuptake inhibitors (SSRIs) are widely prescribed for depression and anxiety in adults. Recent research in children and adolescents indicates some of them can be effective in treating depression, anxiety, obsessive compulsive symptoms, and selective mutism. Regarding one of the SSRIs, paroxetine (Paxil), some reports suggest an increased risk of suicidal behavior in children and adolescents. The Food and Drug Administration advises not to start treatment in children and adolescents with paroxetine, but urges that existing treatment not be interrupted without consultation with a physician (the FDA advisory may be read at <http://www.fda.gov/cder/drug/infopage/paxil/paxilQ&A.htm>).

Tricyclic antidepressants (TCAs), long the most commonly prescribed antidepressants in adults, have been repeatedly shown to be effective in treating depression and anxiety in adults. But research has failed to show benefits from these medications for anxiety disorders or major depression in children and adolescents. Some TCAs are effective in treating other symptoms in children and adolescents, including ADHD symptoms and nocturnal enuresis. Side effects, especially potential cardiac effects and sudden death in a few children and adolescents on desipramine, make TCAs no longer “first-line” treatment for depression.

Among the other antidepressants, the older MAOI’s are not considered “first-line” medications for children and adolescents. Newer MAOI’s do not have the same side effect risks and may be used in the future to treat depression.

Bupropion (Wellbutrin) is an antidepressant that is effective for symptoms of ADHD.

Research with other antidepressants in children and adolescents has not demonstrated effectiveness.

C. Mood Stabilizers

<u>Generic Name</u>	<u>Brand Name</u>
Lithium	Eskalith, Lithonate, Lithobid
Carbamazepine	Tegretol, Carbitrol
Valproate	Depakote
Gabapentin	Neurontin
Lamotrigine	Lamictal
Topiramate.....	Topamax
Oxcarbazepine	Trileptal

Mood stabilizers have been shown to be effective in the treatment of bipolar disorder in adults. There has been less research on their use in treating mania and alleviating emotional instability in children and adolescents. Clinical observations suggest that these medicines may be helpful, especially in adolescents whose symptoms resemble bipolar disorder in adults. Conclusions in this area are made difficult by the infrequency of bipolar disorder in childhood and by controversy regarding its diagnosis and treatment (see below, VI, Areas of Controversy). Some studies have suggested an association of weight gain and endocrine side effects (polycystic ovary syndrome) with valproate use in women.

Another class of mood stabilizers, omega-3 fatty acids, is beginning to be used together with other mood stabilizers in adults. They may be used in the future in children and adolescents.

D. Antipsychotics

Antipsychotic medications reduce psychotic symptoms in children and adolescents with schizophrenia and other psychotic disorders, reduce verbal and motor tics in children and adolescents with Tourette Syndrome, and reduce manic symptoms in adults and children and adolescents. They may also have a role in reducing certain abnormal behaviors in children and adolescents with autism and mental retardation.

Antipsychotic medications come in two classes. Most often used today are a group of newer medications that have fewer and less severe side effects than the older antipsychotics. The names of these medications can be confusing: the newer medications are considered “first-line” (that is, these are the first antipsychotics recommended) but are called “second generation” and “atypical.” The older medications, though considered “second-line” medications today, are called “first-generation” or “typical” because they were discovered first.

First-generation antipsychotics carry significant risk of movement disorders in both the short and long term. Second-generation medications have less risk of this kind, but carry other serious risks (including development of diabetes mellitus, abnormal prolactin secretion, and serious weight gain). Use of one second-generation medication, clozapine (Clozaril) carries a small but definite risk of bone marrow suppression. Patients on clozapine must have a blood test every other week. Weight gain (which increases the risk of diabetes) can be especially troubling with olanzapine (Zyprexa) and clozapine (Clozaril). Quetiapine (Seroquel) can cause cataracts in adults; children and adolescents on this medication should have regular ophthalmologic exams. All antipsychotics can be sedating, sometimes to a degree that interferes with optimal functioning.

First-line agents aka “atypical” or “second-generation”

<u>Generic Name</u>	<u>Brand Name</u>
Risperidone.....	Risperdal
Olanzapine.....	Zyprexa
Clozapine.....	Clozaril
Quetiapine	Seroquel
Ziprasidone	Geodon
Aripiprazole.....	Abilify

Second-line agents

aka “typical” or “first-generation”

<u>Generic Name</u>	<u>Brand Name</u>
Chlorpromazine	Thorazine
Haloperidol	Haldol
Perphenazine	Trilafon
Fluphenazine	Prolixin
Pimozide	Orap

Thiothixene.....	Navane
Molindone	Moban
Loxapine.....	Loxitane
Droperidol	Inapsine
Thioridazine.....	Mellaril

In Massachusetts, the prescription of antipsychotic medication is considered “extraordinary treatment”. Parents can authorize such treatments, but the Department of Social Services (DSS) cannot authorize such treatment for children and adolescents in its custody. For such children and adolescents, a court order (in response to a so-called “Rogers” petition) is required (see page 23 “Informed Consent,” at IV.B.4).

E. Other Medications

<u>Generic Name</u>	<u>Brand Name</u>
Benzodiazepines	
Clonazepam	Klonopin
Lorazepam	Ativan
Alprazolam	Xanax
Others	
Buspirone	Buspar
Clonidine	Catapres
Guanfacine	Tenex
Naltrexone	Revia
Atomoxetine.....	Strattera

A few other medications are currently used in children and adolescents, primarily for the treatment of *anxiety* and/or *impulse control* problems. They include the above listed medications.

Benzodiazepines are used to treat anxiety symptoms and sleep problems in adults; research has provided some support for their use in children and adolescents. People taking these medicines long-term may develop problems with tolerance, dependence, and habituation. These medicines are also subject to non-medical use, which can contribute to excessive sedation and intoxication, especially when combined with alcohol. Some people taking benzodiazepines develop disinhibited behavior or hallucinations. Withdrawal from benzodiazepines can be difficult.

Buspirone can be effective in anxiety in adults, with relatively few side effects. There are no controlled studies with children and adolescents. Clonidine has long been used to treat high blood pressure in adults. It has been used extensively with children and adolescents for treating tics, ADHD, aggressive behavior, and sleep problems. Research support for its use in these

disorders is equivocal. Guanfacine (Tenex) is a newer medication similar to clonidine but longer acting, less sedating, and possibly more effective in improving attention. It is used in treating impulsiveness and hyperactivity associated with ADHD and other disorders. Research has not demonstrated its efficacy.

Atomoxetine (Strattera) is a non-stimulant medication recently approved for treatment of ADHD.

Naltrexone (Revia), an opiate antagonist, is used to treat self-injurious behavior. Beta-blockers like propranolol (Inderal) are used to treat anxiety, especially performance anxiety, and aggressive behavior.

IV. PRINCIPLES OF PRACTICE

A. Assessment

Diagnosis in children and adolescents is complicated by:

- the variety of symptoms in childhood. Categorical diagnoses (like those in DSM-IV) may not fully capture the variety of symptoms in children and adolescents. As a result, children and adolescents often receive multiple diagnoses in an effort to encompass all their symptoms. Even so, families may still feel that the “doctor’s language” doesn’t fit their own ways of thinking about and talking about the troubles of their child or adolescent.
- the fluctuating course of symptoms as children and adolescents grow and mature. In some children and adolescents, well-established symptom pictures remain stable for years. In others, symptoms continually evolve. In still others, intervals of symptoms, even serious symptoms, are preceded and followed by periods of good functioning.

Children and adolescents are referred for psychopharmacological treatment from many settings. They come from schools and pediatrician’s offices; from special education settings; from child welfare and child protection (including DSS); from court, probation, or the Department of Youth Services (DYS) (50% of whose population has previously been exposed to child abuse and neglect); and from mental health settings. Referral is more likely when symptoms persist or are thought unlikely to respond to psychosocial interventions alone.

Symptoms alone, however, may not suffice to bring a child or adolescent to clinical services. Youth from ethnic and racial minorities encounter barriers in seeking and receiving good treatment (Surgeon General’s Report). These barriers include stigma, mistrust, cost, clinical bias, and cultural obstacles.

Psychopharmacological treatment must be part of a comprehensive plan based on a comprehensive assessment. Assessment must include assessment of the child or adolescent, of the family, and of relevant aspects of their world. Data should be gathered in interviews with the child or adolescent and parents (or, absent parents, other caretakers) and from collateral sources (e.g. teachers, protective service workers). Previous medical records should be reviewed. Discussion with the child or adolescent’s primary care physician is indicated.

Assessment of the child or adolescent should identify:

- presenting symptoms, including the child or adolescent’s own words for symptoms,

- current level of functioning,
- developmental history,
- medical history, including history of substance use, previous treatment history, current mental status, and
- history of neglect, abuse, molestation, or other trauma.

Assessment of the family should include:

- family history of mental illness,
- assessment of current functioning and stressors,
- assessment of attitudes toward the child or adolescent's symptoms and needs, including the family's or their culture's ways of describing the child or adolescent, and
- any current or past protective needs.

Assessment of the child's world should describe how the child or adolescent functions with peers and at school. Assessment should identify, for both child or adolescent and family, strengths as well as weaknesses. Assessment of children and adolescents should include description of their attitudes to their symptoms and capacity for alliance with treatment.

Medical assessment of the child or adolescent should assess:

- general health and development,
- well child care, and
- possible contributing medical factors.

Medical assessment should include a physical examination.

A call to the primary care physician will provide much of this information and establish a connection between physicians.

A more detailed, thorough assessment should be offered to children and adolescents with severe symptoms, chronic symptoms, or potential for harm to self or others, and to those for whom ordinary treatment efforts, including extended and/or multiple pharmacotherapy or repeated hospitalizations, have not brought relief. More intensive assessment includes more extensive history from the child or adolescent, family members, and other treating professionals current or past. More intensive assessment may include consultation from specialists in child psychiatry, neurology, neuropsychology, pediatrics, child development, child abuse and neglect, and treatment systems.

Psychological testing should be considered for some children and adolescents to further clarify the child or adolescent's inner life, intellectual capacity, and possible learning problems.

Assessment relies on clinical interviews. In addition, structured methods (like rating scales, questionnaires, and tests) may be used. Commonly used rating scales include the Child Behavior Check List (CBCL), also known as the Achenbach Rating Scale, and the Beck Depression Inventory (BDI), or its pediatric version, the Child Depression Inventory (CDI). All data from rating scales must be interpreted by a clinician. All assessments must recognize the culture of the child or adolescent and family. Assessment and treatment must be appropriately documented and monitored.

Assessment should provide more than a categorical (DSM) diagnosis. Assessment should:

- be open to the adaptive perspective, the idea that the child or adolescent's symptoms, regardless of diagnosis, represent his or her best efforts, given certain inner and outer resources, to cope;
- maintain a developmental perspective, seeing symptoms in the context of longer-term development and adaptation;
- distinguish between transient and longer-term conditions;
- balance accurate description with the fostering of hope;
- balance early detection to facilitate intervention with the risk of inaccurate diagnosis and of adverse effects of labeling.

Clinicians should assess the culture of the child or adolescent relative to their own. When a great difference is present, clinicians should acknowledge such difference and consider the knowledge, skills and attitudes they need in order to provide care. The clinician should understand how values, beliefs, customs, language and communication style influence the perception and expression of mental distress, how they shape help-seeking behavior, and how an alliance can be made in order to develop together a treatment plan.

B. Planning and Contracting for Treatment

Contracting for treatment requires time, attention, and clinical discussion beyond the basic clinical assessment.

Assessment precedes planning. In the plan, the clinician specifies target symptoms and goals, selects a medication for initial use, and schedules visits for evaluating progress. The clinician then recommends treatment, including medication treatment, to the child or adolescent, parent or guardian. Informed consent can then be sought.

1. Articulating Problems, Target Symptoms, and Goals

Assessment identifies relevant diagnoses and treatable symptoms. Diagnoses may help clarify the nature of the child or adolescent's problems and predict their response to treatment.

Treatment is directed to target symptoms, such as anxiety, insomnia, poor concentration, or impulsiveness. Non-descriptive jargon terms like "acting out" or "behavioral issues" are not helpful descriptors. The target symptoms selected should reflect the priorities of the child or adolescent, the family, and others (such as teachers or residential staff) as to which symptoms are most in need of improvement. Target symptoms are not diagnoses; a given symptom might be seen in a variety of disorders. Indeed, a single diagnosis or disorder may contribute to a number of different symptoms. A diagnosis is one context for a symptom, to be taken into consideration along with other contexts, such as presence of developmental disabilities, medical illness, history of abuse, or disruption of caretaking.

Stating target symptoms in child-friendly language helps develop a treatment alliance among doctor, child or adolescent, family, and others. Each party to the treatment should state what he or she hopes medication will do. Each should be helped to understand what changes may realistically be expected. Defining target symptoms also provides a basis for judging the success of the treatment.

It is also helpful to set broader, overall goals for improvement in cognitive, behavioral, or emotional functioning. Goals such as improved overall school performance or peer functioning are too broad to be specific targets for pharmacotherapy. But it helps in defining the overall course of treatment to set such goals and to be clear as to how medication (for example, by improving concentration or reducing social anxiety) may contribute (along with other interventions) to furthering those goals. Distinguishing between improvement (or lack of it) in target symptoms and progress towards overall treatment goals (or lack of it) can help in defining the contribution of medication to overall progress.

Emergent side effects requiring treatment (like acute dystonias or parkinsonian symptoms) should be anticipated in the treatment plan. When they occur, whether anticipated or not, they must be treated promptly.

2. Selecting Agents

A medicine will be recommended to the parent or guardian (usually with the assent and participation of the child or adolescent, according to their developmental level), considering:

- a) the medicines likely to be effective in treating the child or adolescent's disorder;
- b) the actions and side effects of individual medicines within that group;
- c) the likely effects of the medicine on the target symptoms; and
- d) likely side effects or potential toxic effects.

The recommendation of medication should reflect the doctor's best judgment as to the best medication in general and the preferences of child or adolescent and family as to target symptoms and side effects. Physicians should mention medications other than the one recommended and discuss with all parties what alternatives might be considered if the first agent is not effective.

It is best to begin treatment with a single medication. If a single medication proves to be effective, the response can be attributed to that agent and the child or adolescent will have been exposed to less risk of adverse effects. If treatment with a single agent is ineffective, then it is appropriate to try a different single agent or to add an additional medication.

3. Planning Treatment and Monitoring

Monitoring

Having selected a specific medication, the doctor, child or adolescent, family, and others should share their expectations. Questions include the following:

- How soon should the child or adolescent (and other observers) expect to see benefits from taking the medicine?
- What side effects should be expected, and when? What are the most common side effects? Which are the potentially most serious?
- What should the child or adolescent or family do if they notice side effects or other unexpected effects?

- Who should look for indicators of progress or of adverse effects, and how? Will monitoring include any formal assessment, such as checklists or rating scales?
- How will dosage adjustments be made, and in response to which indicators of progress or lack of progress?
- Will laboratory or other medical tests be called for, and how and when should they be done?
- How frequently should follow-up visits take place? In response to which circumstances should more frequent or urgent visits be scheduled?
- Which medical problems might affect the use of the medication?
- What symptoms might be expected when the medicine is stopped?
- Are interactions likely between this medication and others, including illegal substances, that the child or adolescent may be taking?
- How will compliance with taking the medication be assessed, monitored, and assured?
- Is there a risk of abusing this medication, or of developing dependence? How will this risk be managed?

Anticipating problems

In treatment planning one must anticipate what to do if the medicine does not seem or no longer seems to be effective. Acknowledging this possibility at the start of treatment helps prevent disillusionment and increases the chances of continuing collaboration in efforts to find effective medication. If all have agreed on target symptoms and goals, on how to measure progress, and on the expected time course, then the doctor, the child or adolescent, the family and others will know when and how to consider alternatives. Explicit planning also decreases the risk that an ineffective agent will be continued longer than appropriate because of unreasonable initial optimism.

Seeking consultation

The use of expert consultation should be considered if treatment is ineffective. Especially when the prescribing clinician is not a specialist in the treatment of the particular problems involved, it is useful to be prepared early on to seek consultation from someone with more experience. The need for consultation may also arise when the child or adolescent or their family comes from a cultural background markedly different from that of the clinician.

4. Informed Consent

Obtaining informed consent completes treatment contracting. Consent should reflect the elements outlined above. Documentation of consent should specify who gives consent; what information is provided; and how, when, where and to whom consent is given.

Who

Typically, for children and adolescents under age 18, medical treatment, including psychoactive medication, must be authorized by the parent or guardian. Except as noted below, there is no legal requirement that a minor child or adolescent give consent (or even “assent”, that is, implicit consent when a minor takes the medicine) to treatment. Nonetheless, good clinical practice requires that doctor, parent, and others take account of the child or adolescent’s understanding of and attitude towards the treatment and that they gain as much assent as the child or adolescent can give. The appropriate degree of autonomy to afford the minor varies with age, the type and degree of disability, the parent’s attitude, and the urgency of the treatment. In some agencies, some minor children and adolescents are afforded the explicit authority to refuse psychiatric medication. For example, the Department of Youth Services requires both parental consent and child or adolescent assent to medication.

An adolescent 18 or older must give consent to his or her own treatment. Certain adolescents below 18 (emancipated minors and so-called mature minors) also may consent to their own treatment. “Emancipated minor” is defined by statute. The designation of “mature” minor is a clinical decision based on two criteria: the ability of the minor to make an informed decision and the potential harm of informing the minor’s parents or guardian of the decision. This concept is most often employed in cases of abortion, but may also be relevant when a parent and or adolescent disagree on a recommended medication treatment. Court endorsement of the clinical designation may be sought but is not required.

Some children and adolescents require special consent. For children and adolescents in the custody of DSS (but not those in voluntary DSS care or committed to DSS on a CHINS petition), DSS caseworkers consent to “routine treatment.” But by DSS regulation, the prescription of antipsychotic medication is considered to be “extraordinary treatment,” requiring explicit court authorization (following a so-called “Rogers petition”). Children and adolescents in the joint legal custody of parents who disagree about treatment may require court assistance to establish authority to treat.

What

Informed consent should include specific information about the child or adolescent’s condition and the proposed treatment. A DMH policy (96-3R), written for programs funded or operated by the DMH, provides language relevant in all practice settings: Clinicians must “disclose (to the patient and/or their legal guardian)... the significant medical information (as of 2003, “protected health information”)... that is material to an informed decision by the patient as to whether or not to undergo a proposed treatment.” The required information includes:

- indications and target symptoms;
- risks of the recommended medication (including significant, common, and possibly serious or life-threatening side effects);
- reasonably expectable benefits of treatment;
- expectations of the course of illness without treatment;
- reasonable alternatives to treatment;
- expectations about results of interruptions in treatment; and

- expectations concerning the monitoring of treatment.

How

In order to give consent to medical care, a person (or, for a minor, a parent/guardian) must be *competent*. Individuals are presumed competent to make informed decisions unless they are “legally” incompetent (as are children and adolescents under 18), or unless a judge has found them to be incompetent, for instance in a guardianship proceeding. The decision for or against treatment must be a *voluntary* one, made without undue influence from others; it must be based on a *rational* ability to understand facts as presented. A decision to forego treatment may or may not be in the person’s best interests, as those interests are seen by an outsider. Although such decisions are popularly called “*irrational*”, they are valid as long as the person is competent to make the choice. For instance, a refusal of treatment based on religious beliefs may not be rational, but may still be competent. The decision must also be adequately *informed*, as detailed above.

The medical record needs to document the consent process, including who participates, what information has been conveyed, any concerns that may have arisen, and the final giving of consent for the treatment itself. Standardized signature forms may help in documentation, especially if such forms specify the elements noted above. Generic consent forms are neither necessary nor sufficient documentation for the giving of informed consent.

When

Consent for treatment must be obtained before treatment is begun, unless the treatment is considered to be an emergency (see page ____). If treatment is undertaken as an emergency, consent must be obtained as soon as possible; treatment cannot continue beyond the emergency without consent. New consent must also be obtained whenever a different medication is introduced and whenever there is any material change in the circumstances of treatment. Such changes include the emergence of side effects, the development of a relevant medical problem, or other developments affecting the risk/benefit analysis of treatment. Consent for treatment is not a one-time event, but a process that requires ongoing discussion with parent, consenting child or adolescent, or other consenter.

Where

A parent should ideally give consent in a face-to-face interview with the treating clinician. Such contact will provide the best opportunity for careful consideration of the questions needing attention. It is less desirable, but sometimes necessary, to discuss treatment recommendations and obtain consent by telephone, as when treatment is being provided in a residential setting and where it is difficult for parent and clinician to meet in person.

To Whom:

Consent should be given to the clinician prescribing medication. When the prescribing clinician cannot meet personally with the person providing consent, consent may be given by telephone and written note made of it, signed by the clinician.

C. Integration of Treatment

Pharmacotherapy should be coordinated with other interventions. All interventions should comprise an integrated treatment plan. In compliance with Massachusetts Department of Mental

Health (DMH) regulations, treatment providers must obtain authorizations to receive and/or release protected health information except in situations where emergency care is being administered. Authorizations must be signed by the person or entity legally authorized to make health care decisions.

Physicians prescribing medications for children and adolescents should speak to the primary care physician. In addition, clinicians providing psychosocial services, for instance, those helping the child or adolescent with self-understanding and self-management, should be aware of the psychiatric diagnoses and pharmacotherapy. They should help the child or adolescent talk with the prescribing child psychiatrist. Similarly, the child psychiatrist should be aware of psychosocial interventions and use other clinicians' data in assessment and treatment planning. Treatment summaries should reflect each clinician's awareness of the rest of the treatment.

Clinicians' sharing of information and use of a shared language help the child or adolescent make sense of his or her strengths and weaknesses and assist them to feel like a whole person. All members of the team should use the same model of understanding the child or adolescent and of bringing about therapeutic change. Autonomous practitioners working in isolation are unlikely, especially when a child or adolescent has multiple needs, to achieve an integrated view of the child or adolescent.

Treatment summaries should be written so that they can be shared with other clinicians, including primary care clinicians and educators, as appropriate.

D. Communication and Record Keeping

Treatment needs to be summarized in a concise record easily shared from one treatment setting to another, consistent with the requirements of confidentiality. Authorization for the release of protected health information should be obtained routinely as children and adolescents enter services.

The parent or legal guardian of a child or adolescent, including custodial agency, should keep copies of all assessments and treatment summaries so that each new provider can review the child or adolescent's treatment history. Accordingly, the parent or legal guardian should receive all treatment records from providers promptly. Treating clinicians should not prescribe new treatments until they have reviewed summaries of previous assessments and treatment or spoken to prior treaters while awaiting receipt of the records.

E. Continuity of Care

Although the problems requiring pharmacotherapy are not short-term, many children and adolescents are cared for in multiple short-term placements. Frequent movement requires that assessment and treatment information be efficiently transmitted from one setting to the next. The possibility that frequent changes of residence and caregivers may exacerbate the child or adolescent's symptoms should be considered as a possible factor contributing to the child or adolescent's problems. The goal should be to provide continuity of treatment, including medication and relationships, as the child or adolescent recovers.

Discontinuity of care may be a special problem for children and adolescents entering the custody of the Department of Social Services or detained in a Department of Youth Services (DYS) facility. Clinicians prescribing psychoactive medications for children and adolescents should be familiar with different agencies' regulations regarding the use of antipsychotic medications.

Specifically, if a child or adolescent is taking an antipsychotic medication without judicial review at the time he or she comes under DSS custody, clinicians and others should be alert to the risks of abruptly stopping psychoactive medication and so advise those with responsibility for the child or adolescent's care. The same considerations apply when children and adolescents on psychoactive medication enter a DYS facility. Interruption or discontinuation of that treatment might cause psychological deterioration and might violate the individual's legal right to treatment.

V. AREAS OF CONTROVERSY

There are a number of areas where child psychiatrists are still working to achieve consensus. In other areas, public opinion is divided. Clinicians should teach parents, guardians, and children and adolescents that different practitioners may approach the same problem differently.

A. Attention Deficit-Hyperactivity Disorder

Attention Deficit-Hyperactivity Disorder (ADHD), although one of the oldest and most studied disorders in child psychiatry, is often misunderstood. Typical ADHD symptoms in school-age children and adolescents (restlessness, distractibility, poor attention) resemble the normal behavior of younger children. Controversy exists as to the diagnosis of ADHD and the use of stimulants in children under five. Moreover, considerable misleading and inaccurate information about ADHD and stimulant therapy has been distributed, some of it coming from religious and political groups opposed to all biological treatments in psychiatry. Nonetheless, ADHD is different from normal behavior. Children and adolescents with ADHD are at increased risk for academic, social, and legal problems. A consensus statement developed by the National Institutes of Health concluded that ADHD is a valid disorder with considerable costs to individuals and society. Effective treatments exist for ADHD, stimulants being more effective than psychosocial treatments. There is no known prevention for ADHD.

Evidence exists that stimulant medication helps children and adolescents with ADHD to concentrate and focus better. Recent evidence shows stimulant medication to be as good as or better than behavioral treatment alone. Options in treating ADHD have increased with the demonstration that clonidine (Catapres) and guanfacine (Tenex), alpha-adrenergic agonists, in addition to the stimulants, can be effective in ADHD, especially for hyperactivity, and with the introduction of a non-stimulant medication for ADHD.

Despite this evidence, many children and adolescents meeting diagnostic criteria for ADHD get no treatment. The Surgeon General (1999) reports that, while ADHD occurs in 3 to 5 percent of school-age children, only 2 to 3 percent of school-aged children are being treated for ADHD.

MEDICATIONS USED IN ATTENTION DEFICIT-HYPERACTIVITY DISORDER (ADHD)

STIMULANTS

Short-acting:

Methylphenidate (Ritalin)
Dextroamphetamine (Dexedrine)
Pemoline (Cylert)

Intermediate-acting:

Sustained-Release Methylphenidate (Metadate ER)
 Methylin ER
 Ritalin SR

Long-acting:

Concerta
 Sustained-Release Methylphenidate (Metadate CD)
 Dexedrine Spansules
 Amphetamine Mixture (Adderall XR)

ALPHA-ADRENERGIC AGENTS

Clonidine (Catapres)
 Guanfacine (Tenex)

ANTIDEPRESSANTS

SSRIs, TCAs, Bupropion (Wellbutrin) (see pages 11 & 12)

OTHER

Atomoxetine (Strattera)

Several points bear emphasis. First, children and adolescents with ADHD tend to have other disorders as well. Accordingly, those treating children and adolescents with ADHD may make several diagnoses and recommend more than one medicine. Second, several factors make it hard to concentrate. The child or adolescent who is hungry, or who is worried about his or her safety, or who has flashbacks or thought disorganization, or whose school program does not match his or her needs, will have difficult attending to schoolwork. Amid such other possibilities, the possible role of ADHD must be carefully assessed, and neither assumed nor excluded too easily. Third, the benefit of stimulant medication may only become apparent when external and internal turmoil has subsided. That is, a child or adolescent may benefit from stimulants, but not while being abused or neglected and not while in an acute psychotic state. The child or adolescent who does not appear to benefit from stimulants at such a time may, when the other problems improve, benefit. Medication treatment for ADHD should not be undertaken as if the other problems did not exist. Fourth, in a child or adolescent receiving multiple agents, the interaction between the agents must be carefully monitored.

With ADHD as with other disorders, different clinicians, even with the same data, may make different recommendations as to what level of symptoms requires treatment.

B. Bipolar Disorder

Considerable clinical and epidemiological research supports the idea that bipolar disorder occurs in children and adolescents. Its features include emotional lability, especially tantruming, as well

as hypersexuality and suicidal behavior. Treatment with mood stabilizers may be helpful. Clinicians disagree about the criteria for this diagnosis in children and adolescents and in recommending treatment with mood stabilizers. A family history of bipolar disorder in a child or adolescent presenting with serious problems with mood or temper regulation warrants close monitoring of any antidepressant use and consideration of a trial of a mood stabilizer. Inappropriate diagnosis of bipolar disorder, on the other hand, may expose the child or adolescent to unwarranted medication and undercut the child or adolescent's efforts at self-understanding and self-management. When a child or adolescent, or the family, say, "I'm (he's) bipolar-" they may stop thinking about the course, meaning, and management of mood changes.

Related to bipolar symptoms is so-called "antidepressant activation." This term is used when the child or adolescent taking an antidepressant develops increased activity, irritability, insomnia, hypersexuality, grandiosity, hallucinations or rapid talking. Such activation does not make the diagnosis of bipolar disorder, nor predict its emergence later; it may just be a medication side effect unrelated to bipolar disorder. Some children and adolescents may benefit from antidepressant medication but only when also taking a mood stabilizer. For such children and adolescents, a mood stabilizer may be prescribed along with an antidepressant.

C. Use of Antipsychotics (aka Neuroleptics)

Some clinicians prescribe antipsychotic agents only for frank psychotic thought disorder. Others argue for a broader range of use in children and adolescents, helping children and adolescents with severe, disabling disorganization or uncontrollable emotional flooding. While second-generation agents have less toxicity than do earlier antipsychotic agents [see page 14 III D, and BOX: Second-generation agents], these medications still have considerable side effects. Their prescription is not to be undertaken lightly.

Caution should be exercised that antipsychotic medications are not prescribed for children and adolescents in lieu of acknowledging and treating the other challenges they face. Many challenges, like unrecognized abuse or molestation, or post-traumatic states, severe caretaking deficits, unrecognized visual or hearing impairment, or other learning disability, or unacknowledged family conflict, can result in children and adolescents feeling overwhelmed. Too hasty assessment of such children and adolescents can result in injudicious prescription of possibly unwarranted medication as well as delay in recognizing and addressing other adversities in the life of the child or adolescent.

On the other hand, when the efforts of the child or adolescent to cope with adversity are compounded by inner disorganization, environmental interventions may still leave them too disorganized to take advantage of the opportunities available. A trial of antipsychotic medication may dramatically enhance such individuals' ability to cope.

Careful watch should be kept in such cases to demonstrate that a comprehensive plan, not just medication, is being offered; that the use of antipsychotic medication has indeed made a difference in the child or adolescent's coping; and that such use, once thought to be helpful, is continued no longer than necessary.

D. Post-Traumatic States

While we know much about post-traumatic symptoms in children and adolescents, researchers are still evaluating what are the best treatments for traumatized children and adolescents. Treatment options include psychotherapy, especially cognitive-behavior therapies (CBT), pharmacotherapy

and the newer somatic therapies such as eye-movement desensitization and reprocessing (EMDR). Agents like clonidine and the SSRIs (fluoxetine, etc) help children and adolescents cope with the symptomatic sequelae of trauma. The use of such medications in children and adolescents rests on clinical experience, not on controlled clinical research trials.

Abused and neglected children and adolescents often present with symptoms of extreme fragility, withdrawal, aggression and mood instability that do not meet full criteria for PTSD but which require intervention. Treatment for such children and adolescents should include careful psychotherapy by experienced therapists and not be limited to the use of medications.

Symptoms such as “hearing voices” are often present in traumatized children and adolescents. Such hallucinosis is not in itself an indicator of psychotic illness and may not require anti-psychotic medications, with the attendant risks. Children and adolescents with a history of trauma may also respond to subtle reminders of the trauma with behavioral outbursts and emotional instability resembling that seen in affective disorders. Mood stabilizers, accompanied by fewer risks than the anti-psychotics, may be helpful in such children and adolescents.

A thorough assessment of the child or adolescent, noting current and past trauma, is necessary to identify factors that may respond to medications as well as those that require psychotherapy and environmental interventions.

E. Children and Adolescents with Developmental Disabilities

Psychiatric symptoms in children and adolescents with developmental disabilities present many clinical challenges, including whether to use medication. It is unclear which diagnostic criteria should be used in this population, especially in children and adolescents with IQ's below 50. Diagnostic uncertainty notwithstanding, children and adolescents with developmental disabilities are more likely to have multiple disorders.

Developmentally delayed children and adolescents with psychiatric symptoms should have a thorough assessment in a multidisciplinary setting and should be offered multimodal therapy with emphasis on specialized behavioral interventions.

There is a dearth of information about the safety and efficacy of psychoactive medications in children and adolescents with developmental disabilities; there are only a small number of methodologically sound studies. Many agents have been recommended; few have been shown to be effective in controlled trials. Nevertheless, depending on the circumstances of the individual child or adolescent (and possible associated psychiatric comorbidity), antipsychotics or mood stabilizers may be recommended. A recent well-designed study demonstrated positive role for risperidone (Risperdal) in children with developmental disorders.

Pharmacological intervention is often recommended to treat aggressive or self-injuring behavior that is so intense, frequent or persistent as to threaten the child or adolescent or those nearby, or behavior that is so disruptive as to prevent the child or adolescent from using school or occupational, physical, speech, or interactional therapies. Except in emergencies (see page 35), clinicians should not prescribe something immediately, “to take the edge off” the challenging behaviors, in lieu of a diagnostic assessment that will complete the overall picture of the child or adolescent, including delineation of the factors that contribute to the behavior. Parents, teachers, and other caregivers may need considerable support during this phase, in order to ensure their cooperation with the recommended treatment plan.

It is advisable to treat each case on an individual basis, “as a single case study, starting with the safest and most commonly used medications in low doses and increasing the dose gradually” (Santosh & Baird, 1999). Continued treatment or revision of the plan will be guided by adults’ reports of behavioral changes, the child or adolescent’s subjective reaction to the medication (if they are able to provide this information), and the child or adolescent’s tolerance for side-effects as well as any idiosyncratic reactions to the medication.

F. Extreme Behavioral Dyscontrol (Aggressive and Self-Injurious)

The principle that medication treatment in children and adolescents is based more often on clinical experience than on controlled clinical trials is especially true when dealing with children and adolescents with aggressive or self-harming behavior that threatens their own or others’ safety. For many such children and adolescents, the need for urgent intervention is often clearer than the diagnosis. With or without diagnostic clarity, medication is often an important part of their treatment. Such treatment must, like any treatment, be part of a carefully developed plan based on comprehensive assessment. When the diagnosis is uncertain, specifying the factors that contribute to the problem may help to summarize a formulation and guide treatment. Target symptoms should be identified, as in any other treatment, and agents judiciously introduced, with the results monitored according to an agreed-upon plan.

In assessment, one should examine the context in which the behavior is occurring; medication should never be prescribed for a child or adolescent with extreme behavioral dyscontrol without an inquiry into context and interactions. Assessment should also be alert to the possibility of undiagnosed medical disorder (endocrine-metabolic or toxic), of substance use including caffeine or withdrawal from nicotine, and of unrecognized psychiatric disorder, such as post-traumatic or other anxiety disorder, depression or bipolar disorder, or unrecognized psychosis.

In prescribing any agent for extreme behavioral dyscontrol, the clinician should balance the urgency of the situation against the desirability of acquiring more understanding before taking action. He or she should also consider whether the treatment will constitute an emergency, and, if so, whether treatment will be voluntary or involuntary (see page 35).

In general, pharmacological treatment of extreme behavioral dyscontrol starts with less toxic, shorter-acting agents: sedatives (like diphenhydramine [Benadryl and others]), alpha-agonists and beta-blockers. Longer-acting agents and those with more side effects (mood stabilizers, antidepressants, naltrexone [Revia], antipsychotics) are recommended either when a specific disorder is diagnosed (e.g., depression, bipolar disorder, or psychosis) or as an empirical trial when shorter-acting or less toxic agents have failed or are deemed unlikely to be effective.

G. Involuntary Treatment

Although this guideline is written as if medication treatment always occurs in response to the voluntary assent (by child or adolescent or guardian) to a proposed treatment, *involuntary* treatment also occurs.

A competent child or adolescent or parent/guardian has the right to refuse treatment. Therefore, involuntary treatment may be given only when the court has found the parent/guardian to be incompetent to provide informed consent or when a court finds that the parent/guardian is endangering the child or adolescent as in a life-threatening situation.

When a parent/guardian gives informed consent for treatment and the minor child or adolescent refuses treatment, it is incumbent upon the treating clinician to attempt to gain the minor's assent (although there is no legal obligation to do so). If a parent or legal guardian refuses to consent to treatment, and if a clinician judges that this refusal places the well-being of the child or adolescent in jeopardy, the clinician should consider seeking assistance from the DSS or asking the court to appoint a new guardian.

There are two types of *emergency* involuntary treatment. In chemical restraint, medication is given involuntarily in order to restrain a child or adolescent. Medication may also be given involuntarily to prevent immediate, substantial and irreversible deterioration of serious mental illness.

Chemical restraint, like all forms of restraint, may only be used in emergencies, when extreme violence, personal injury, or attempted suicide has occurred or been threatened. Such measures can be used only when there is a substantial risk of serious self-destructive behavior or of serious physical assault or when a serious physical assault has occurred. A child or adolescent may be given chemical restraint only on the order of an authorized physician. This physician must have determined, either while present at the time or after telephone consultation with a physician, registered nurse or certified physician assistant who was present at the time of the emergency and who has personally examined the child or adolescent, that such chemical restraint is the least restrictive, most appropriate alternative available. (See DMH Regulations 104 CMR 27.12) [In schools, the use of mechanical or chemical restraint is regulated by the Department of Education, which requires authorization by physician and parent.]

Apart from situations requiring use of restraint, emergency treatment occurs very infrequently. It may occur only when the physician believes that delaying treatment in order to obtain a court order for the treatment poses the risk of the substantial and irreversible deterioration of the child or adolescent's serious mental illness. There are very few instances in which this threshold is met.

H. Adverse Side Effects

All prescribing child psychiatrists and other clinicians are concerned about possible adverse side effects of medication. Opinions differ as to how to weigh the advantages and disadvantages of a course of treatment in a given child or adolescent. The final decision, of course, rests with the parent or guardian, with the advice of clinicians.

VI. CLIENT/PARENT EDUCATION

The following books, articles, and websites have been identified as particularly helpful resources for clients and families.

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PSYCHOACTIVE MEDICATION FOR CHILDREN AND
ADOLESCENTS:
ORIENTATION FOR PARENTS, GUARDIANS, AND OTHERS

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